Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 241

Report Date:10/04/2007

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory	050510914	09/24/98	726	50 (1)	37(710)	53.4	Triethanolamine
				Fen	nale		
Battelle Columbus Laboratory	050510914	09/23/98	729	50 (1)	35(692)	62.7	Triethanolamine

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 242

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: **Benign Tumors** 30/50 (60%)24/50 (48%)#All Organs: **Malignant Tumors** 28/50 (56%)27/50 (54%)#All Organs: **Malignant and Benign Tumors** 45/50 (90%)38/50 (76%) #All Organs: Hemangioma 1/50 (2%)1/50 (2%)#All Organs: Hemangiosarcoma 3/50 (6%)3/50 (6%)#All Organs: Hemangiosarcoma or Hemangioma 4/50 (8%) 4/50 (8%) #All Organs: **Histiocytic Sarcoma** 0/50 (0%)(8%) 4/50

8/50

(16%)

Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS,

0/50

(0%)

or Undifferentiated Cell Type

#All Organs:

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 243

Report Date: 10/04/2007

		Male		Female
#All Organs: Mesothelioma: Benign, Malignant, NOS	0/50	(0%)	0/50	(0%)
#All Organs: Mesothelioma: Malignant	0/50	(0%)	0/50	(0%)
#All Organs: Osteoma	0/50	(0%)	0/50	(0%)
#All Organs: Osteosarcoma	1/50	(2%)	1/50	(2%)
#All Organs: Osteosarcoma or Osteoma	1/50	(2%)	1/50	(2%)
*Adrenal Cortex: Adenoma	3/50	(6%)	0/50	(0%)
*Adrenal Cortex: Sarcoma	0/50	(0%)	0/50	(0%)
*Adrenal Medulla: Pheochromocytoma Benign	1/50	(2%)	1/49	(2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 244

Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
*Adrenal Medulla: Pheochromocytoma Complex	0/50	(0%)	0/49	(0%)
*Adrenal Medulla: Pheochromocytoma Malignant	0/50	(0%)	0/49	(0%)
*Adrenal Medulla: Pheochromocytoma: Benign, Complex,			1/49	(2%)
*Bone Marrow: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
*Bone Marrow: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
#Bone: Osteoma	0/50	(0%)	0/50	(0%)
#Bone: Osteosarcoma	1/50	(2%)	0/50	(0%)
#Bone: Osteosarcoma or Osteoma	1/50	(2%)	0/50	(0%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 245

Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male	Female
#Bone: Sarcoma 0/50) (0%)	0/50 (0%)
*Brain: Schwannoma Malignant 0/50) (0%)	0/50 (0%)
*Clitoral/Preputial Gland: Adenoma 0/50		0/50 (0%)
*Clitoral/Preputial Gland: Carcinoma 0/50) (0%)	0/50 (0%)
*Clitoral/Preputial Gland: Carcinoma or Adenoma 0/50		0/50 (0%)
*Clitoral/Preputial Gland: Hemangiosarcoma 0/50) (0%)	0/50 (0%)
*Clitoral/Preputial Gland: Squamous Cell Carcinoma 0/50		0/50 (0%)
*Epididymis: Sarcoma 0/50		

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 246

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Eye: Sarcoma 0/50 (0%)(0%)*Gallbladder: Adenoma 0/48 (0%)0/48 (0%)#Harderian Gland: Adenoma 7/50 (14%)5/50 (10%)#Harderian Gland: Carcinoma 0/50 (0%)2/50 (4%)#Harderian Gland: Carcinoma or Adenoma 7/50 (14%)7/50 (14%) *Heart: Hemangioma 0/50 (0%)0/50 (0%)*Heart: Hemangiosarcoma 0/50 (0%)(2%)1/50 *Heart: Sarcoma 0/50 (0%)0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 247

Report Date: 10/04/2007

	Male		Female
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
	0/50 0/50 0/50 0/50 0/50	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 248

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Jejunum: Adenoma 0/50 (0%)(0%)#Intestine Small: Jejunum: Carcinoma 3/50 (6%)0/50 (0%)#Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)0/50 (0%)#Intestine Small: Jejunum: Leiomyosarcoma (0%)0/50 0/50 (0%)#Intestine Small: Jejunum: **Polyp Adenomatous** 0/50 (0%)0/50 (0%) #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)#Intestine Small: Site Unspecified: Carcinoma 3/50 (6%)0/50 (0%)#Intestine Small: Site Unspecified: Carcinoma or Adenoma 3/50 (6%)0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 249

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
#Intestine Small: Site Unspecified: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Leiomyosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Polyp Adenomatous	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Adenoma	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Carcinoma	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Kidney: Renal Tubule: Adenoma	1/50	(2%)	0/50	(0%)
*Kidney: Renal Tubule: Carcinoma	0/50	(0%)	0/50	(0%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 250

(12%)

6/50

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%)(0%)*Liver: Cholangiocarcinoma 0/50 (0%)0/50 (0%)**Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)*Liver: Hemangioma (0%)0/50 1/50 (2%)*Liver: Hemangiosarcoma 1/50 (2%)0/50 (0%) *Liver: Hepatoblastoma (2%) 1/50 0/50 (0%)*Liver: Hepatocellular Adenoma (38%)(18%)19/50 9/50 *Liver:

(34%)

17/50

Hepatocellular Carcinoma

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 251

Report Date: 10/04/2007

		Male		Female
*Liver: Hepatocellular Carcinoma or Hepatoblasto	oma 18/50	(36%)	6/50	(12%)
*Liver: Hepatocellular Carcinoma or Hepatocellula	33/50	(66%)	12/50	
*Liver: Hepatocellular Carcinoma, Hepatocellular A Hepatoblastoma	Adenon	na, or (66%)	12/50	
*Liver: Hepatocholangiocarcinoma	0/50	(0%)	0/50	(0%)
*Liver: Ito Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
*Liver: Sarcoma	0/50	(0%)	0/50	(0%)
*Lung: Adenoma	0/50	(0%)	0/50	(0%)
*Lung: Alveolar/Bronchiolar Adenoma	6/50	(12%)	3/50	(6%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 252

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Lung: Alveolar/Bronchiolar Carcinoma 7/50 (14%)(4%)Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 12/50 (24%)(10%)*Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)*Lung: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)*Lung: Hemangiosarcoma 0/50 (0%)0/50 **#Lymph Node: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)#Lymph Node: Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Lymph Node:** Sarcoma 0/50 (0%)0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 253

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Lymph Node, Bronchial: Hemangiosarcoma 0/50 (0%)(0%)#Lymph Node, Mandibular: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)#Lymph Node, Mediastinal: Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Lymph Node, Mesenteric: Fibrous Histiocytoma** (0%)(0%)0/50 0/50 **#Lymph Node, Mesenteric:** Hemangiosarcoma 0/50 (0%)0/50 (0%) #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)#Mammary Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 254

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mesentery: Fibrosarcoma 0/50 (0%)(0%)#Mesentery: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)#Mesentery: Hemangioma 0/50 (0%)0/50 (0%)#Mesentery: Hemangiosarcoma 0/50 (0%)(0%)0/50 #Mesentery: Leiomyosarcoma 0/50 (0%)0/50 (0%) #Mesentery: Sarcoma (0%) 0/50 0/50 (0%)*Nose: Carcinoma 0/50 (0%)0/50 (0%)*Nose: Hemangioma 0/50 (0%)(0%)0/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

: SKIN

Page: 255

Report Date:10/04/2007

		Male		Female
*Nose: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
*Nose: Sarcoma	0/50	(0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Papilloma Squamous or Papilloma	0/50	(0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Squamous Cell Carcinoma	x, Tooth, 0/50	Gingiva): (0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Squamous Cell Carcinoma, Papilloma S Papilloma		Gingiva):	0/50	(0%)
#Oral Mucosa: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
*Ovary: Choriocarcinoma			0/50	(0%)
*Ovary: Cystadenoma			1/50	(2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 256

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Fibrous Histiocytoma (0%)*Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Granulosa Cell Tumor Malignant** 0/50 (0%)*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS (0%)0/50 *Ovary: Hemangioma 0/50 (0%) Hemangiosarcoma 0/50 (0%)*Ovary: Leiomyosarcoma 0/50 (0%)*Ovary: Luteoma (2%)1/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 257

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Ovary: **Teratoma Benign** (0%)*Ovary: **Tubulostromal Adenoma** 0/50 (0%)*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)*Pancreas: Carcinoma or Adenoma (0%)0/50 0/50 (0%)*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/50 (0%)8/50 (16%)*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 (0%)*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma (16%) (0%)0/50 8/50 *Pituitary Gland: Pars Intermedia: Adenoma

0/50

(0%)

(2%)

1/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 258

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Male Female *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 1/50 (2%)(0%)*Prostate: Adenoma 0/50 (0%)*Prostate: Carcinoma or Adenoma 0/50 (0%)*Salivary Glands: Carcinoma 0/50 (0%)0/50 (0%)*Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/50 (0%) **#Seminal Vesicle:** Adenoma 0/50 (0%)**#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Skeletal Muscle:** Rhabdomyosarcoma (0%) 0/50 (2%)1/50

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 259

Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma				
	0/50	(0%)	1/50	(2%)
#Skeletal Muscle: Sarcoma	0/50	(0%)	0/50	(0%)
		(070)		(070)
#Skin: Basal Cell Adenoma or Basosquamous Tu				
	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Adenoma, Basosquamous Tum Trichoepithelioma	or Beni	jn, or		
onoopunonema	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Carcinoma or Basosquamous 7 NOS)	Γumor (ι	nalignant or		
	0/50	(0%)	0/50	(0%)
#Skin:	• • • • • • • • • • • • • • • • • • • •			
Basal Cell Carcinoma, Basal Cell Adenom Tumor (benign, malignant or NOS), or Tric	a, Baso hoepith	quamous elioma (0%)	0/50	(0%)
		(070)	0/30	(070)
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, I	Basosq.	Tumor (M		
or B), Basal Cell Adenoma, Adenoma, Pap Papilloma, Keratoacanthoma, Trichoepith	illoma,		0/50	(0%)
	0/30	(070)	0/30	(070)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 260

Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

0/50	(0%)	0/50	(0%)
			(5,0)
0/50		0/50	(0%)
0/50	(0%)	1/50	(2%)
0/50	(0%)	1/50	(2%)
0/50		1/50	(2%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	1/50	(2%)
	0/50 0/50 Fibrous 0/50 0/50 0/50	a, Myxosarcoma, or 0/50 (0%) 0/50 (0%) Fibrous 0/50 (0%) 0/50 (0%) 0/50 (0%)	a, Myxosarcoma, or 0/50 (0%) 1/50 0/50 (0%) 1/50 Fibrous 0/50 (0%) 1/50 0/50 (0%) 0/50 0/50 (0%) 0/50

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 261

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 262

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Schwannoma Malignant 0/50 (0%)(0%)#Skin: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)#Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Squamous Cell Papilloma or Papilloma** 0/50 (0%)0/50 #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (0%)0/50 0/50 #Skin:

0/50

1/50

(2%)

0/50

(0%)

Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

#Skin: Sebaceous Gland: Adenoma

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 263

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Sebaceous Gland: Carcinoma or Adenoma 0/50 (0%)(2%)**#Spinal Cord:** Meningioma Malignant 0/50 (0%)0/50 (0%)*Spleen: **Fibrous Histiocytoma** 0/49 (0%)0/50 (0%)*Spleen: Hemangioma 1/49 (2%)0/50 (0%)*Spleen: Hemangiosarcoma 2/49 (4%)1/50 (2%)#Stomach, Forestomach: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)#Stomach, Forestomach: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 1/50 (2%)2/50 (4%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 264

Report Date:10/04/2007

	Male		Female
4/50	(00)	0/50	400
	(2%)	2/50	(4%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)		
0/50	(0%)		
0/50	(0%)		
	(0%)		
	0/50 0/50 0/50 0/50	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 265

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
*Thymus: Thymoma Malignant	0/48	(0%)	0/49	(0%)
*Thymus: Thymoma: Benign, Malignant, NOS	0/48	(0%)	0/49	(0%)
*Thyroid Gland: Adenoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: C-Cell: Carcinoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: Follicular Cell: Adenoma	1/50	(2%)	0/50	(0%)
*Thyroid Gland: Follicular Cell: Carcinoma	0/50	(0%)	1/50	(2%)
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	1/50	(2%)	1/50	(2%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 266

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
#Tissue NOS: Carcinoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Schwannoma Malignant	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma or Papillo			0/50	(0%)
#Tongue: Squamous Cell Papilloma	0/50	(0%)	0/50	(0%)
#Tooth: Odontoma	1/50	(2%)	0/50	(0%)
*Urinary Bladder: Hemangioma	0/50	(0%)	0/50	(0%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 267

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Hemangiosarcoma 0/50 (0%)(0%)#Uterus: Adenoma 0/50 (0%)#Uterus: Carcinoma 0/50 (0%)#Uterus: Deciduoma Benign (0%)0/50 #Uterus: Hemangioma 0/50 (0%) **#Uterus:** Hemangiosarcoma 0/50 (0%)#Uterus: Leiomyoma 0/50 (0%)#Uterus: Leiomyosarcoma (0%)0/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ACETONE Page: 268

Report Date:10/04/2007

	Male	Female
#Uterus: Polyp Stromal		1/50 (2%)
#Uterus: Sarcoma Stromal		0/50 (0%)
#Uterus: Sarcoma Stromal or Polyp Stromal		1/50 (2%)
#Uterus: Schwannoma Malignant		0/50 (0%)
#Vagina: Squamous Cell Carcinoma		0/50 (0%)
#Vagina: Squamous Cell Papilloma		0/50 (0%)
#Zymbal's Gland: Carcinoma	0/50 (0%)	0/50 (0%)
#Zymbal's Gland: Carcinoma or Adenoma	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied